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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,125	11/21/2001	Keith Henry Stockman Campbell	07681.0017-01	1809

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EXAMINER

CROUCH, DEBORAH

ART UNIT PAPER NUMBER

1632

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,125

Applicant(s)

CAMPBELL ET AL.

Examiner

Deborah Crouch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *detailed action*.

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Applicant's request for an interference is noted. However, the Board of Interferences will not accept any case for interference where there are outstanding rejections. Once the rejections below are overcome, this file will be forwarded to the Board of Interferences.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-18 of U.S. Patent No. 6,252,133 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and those of '133 are of overlapping scope.

Present claim 19 is drawn to a method of cloning a nonhuman mammal by nuclear transfer comprising inserting the nucleus of a nonhuman mammalian differentiated somatic cell in the G1 phase of the cell cycle into an enucleated MII oocyte of the same species, maintaining the embryo, activating the embryo, culturing the activated embryo to a blastocyst and transferring the cultured embryo to a host non-human mammal of the same species such that the cultured embryo develops to term.

Claims 11-18 of '133 are drawn to methods of reconstructing an embryo of a nonhuman mammal comprising transferring the nucleus of a donor cell in the G0 or G1 phase of the cell cycle into an unactivated, enucleated MII oocyte without activating the oocyte, maintaining the embryo in the presence of at least one microtubule stabilizer to

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maintain ploidy, and activating and maintaining the reconstructed embryo in the presence of at least one microtubule inhibitor, and methods of producing a nonhuman mammal comprising transferring the embryo to a female mammal of the same species, where the transfer is by cell fusion and the donor nucleus is genetically modified.

Present claim 19 is obvious over claims 11-18 of '133. The present language that the donor cell would have passed start and be in G1 is obvious over the donor cell of '133 being in G1 as to arrive at G1 the donor cell of '133 would have had to pass start. Further the specification of '133 defines donor cells as including nonhuman mammalian differentiated somatic cells. The present specification defines that the maintaining of the embryo can be in the presence of at least one microtubule stabilizer, that the transfer can be by cell fusion and that the donor nucleus can be genetically modified. Thus at the time of the instant invention, it would have been obvious to the ordinary artisan to clone a nonhuman mammal by the presently claimed method given the method claimed in '133.

Claim 19 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 09/989,126. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of overlapping subject matter.

Present claim 19 is drawn to a method of cloning a nonhuman mammal by nuclear transfer comprising inserting the nucleus of a nonhuman mammalian differentiated somatic cell in the G1 phase of the cell cycle into an enucleated MII oocyte of the same species, maintaining the embryo, activating the embryo, culturing the activated embryo to a blastocyst and transferring the cultured embryo to a host non-human mammal of the same species such that the cultured embryo develops to term.

Claim 19 of '126 is drawn to a method of producing a nonhuman mammalian embryo by nuclear transfer comprising transfer of a nucleus of a nonhuman mammalian

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differentiated cell into an unactivated, enucleated metaphase II-arrested oocyte of the same species as the donor cell, activating the oocyte, and incubating the oocyte to provide an embryo.

Present claim 19 is obvious over claim 19 of '126. The presently method of cloning a nonhuman mammal requires the method of producing a nonhuman mammal embryo of '126. The present claim states that the donor cell is a mammalian differentiated somatic cell. The mammalian differentiated cells of claim 19 in '126 encompass this category of cells. Further, in order for the cells of '126 to be past start and in G1, the cells of '126 would have had to pass start as presently claimed. The present specification defines a use for the claimed embryos in the production of cloned mammals. Therefore at the time of the instant invention, it would have been obvious to the ordinary artisan to arrive at the presently claimed methods of cloning a nonhuman mammal given claim 19 of '126.

Claim 19 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 09/989,128. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are of overlapping subject matter.

Present claim 19 is drawn to a method of cloning a nonhuman mammal by nuclear transfer comprising inserting the nucleus of a nonhuman mammalian differentiated somatic cell in the G1 phase of the cell cycle into an enucleated MII oocyte of the same species, maintaining the embryo, activating the embryo, culturing the activated embryo to a blastocyst and transferring the cultured embryo to a host non-human mammal of the same species such that the cultured embryo develops to term.

Claim 19 is drawn to a method of producing a nonhuman mammal embryo by nuclear transfer comprising transferring a nucleus of a nonhuman mammalian differentiated cell which has passed start in the mitotic cycle and is in the G1 phase of the cell cycle into

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an unactivated enucleated MII oocyte of the same species as the donor cell, activating the oocyte, and incubating the oocyte to provide an embryo.

Present claim 19 is obvious over claim 19 of '128. Present claim 19 states that the donor cell is a mammalian differentiated somatic cell. The mammalian differentiated cells of '128 encompass this category of cell. The present specification defines the use of the presently claimed embryo in the production of a cloned nonhuman mammal. Thus, it would have been obvious to the ordinary artisan at the time of the instant invention to arrive at the presently claimed methods of cloning a nonhuman mammal given claim 19 of '128.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is confusing as step (v) states that the cultured, reconstituted embryo is transferred. However, step (iv) states that the reconstituted embryo is cultured to a blastocyst. The confusion lies in the use of the blastocyst.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. R. Clark can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dc
February 23, 2002